2 June 2020
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Stakeholders and Communication Division

Meeting summary - PCWP/HCPWP joint meeting

2 June 2020, 12:45hrs to 17:45hrs – Virtual meeting

Co-Chairs: J. Garcia Burgos (EMA), K. Immonen (PCWP), U. Jäger (HCPWP) via Adobe

Welcome and introduction

Juan Garcia-Burgos opened the meeting and welcomed all the participants.

Juan described the focus of the meeting; the Agency's activities in relation to COVID-19, shortages and availability of medicines and finally data protection and the development of a Q&A on the secondary use of healthcare data. He highlighted that the meeting was being recorded and the first two sessions will be published in the next few days.

The co-chairs; Ulrich Jäger and Kaisa Immonen introduced themselves and welcomed the participants.

1. COVID-19 pandemic response

1.1 Agency's contribution to the pandemic response

Noel Wathion, EMA's Deputy Executive Director and EMA COVID-19 taskforce lead.

Noel gave an overview of the Agency's contribution to the pandemic response (see presentation and recording). He explained that EMA rapidly set up a taskforce on COVID-19 in order ensure that all COVID-related challenges are handled in the most efficient manner possible. The taskforce is comprised of 4 workstreams; 1) Therapeutic response, 2) Supply chain, 3) Business continuity and impact and 4) Human resources. The presentation covered mainly aspects related to 1) and 2) as streams 3) and 4) are more about coping with the increase in workload in relation to COVID-19 in addition to EMA's usual activities.

1.2 Update on treatments and vaccines under development

Marco Cavaleri, head of health threats and vaccines strategy at EMA, gave an update on treatments and vaccines under development for COVID-19 (see presentation and recording).

Marco explained that the focus at the beginning of the pandemic was essentially to understand what kind of antiviral agents could be rapidly used and repurposed to treat COVID-19. It has then become clearer that that this is a very complex disease with different stages; the early phase is dominated by viral replication, then the inflammatory response tends to be the most critical aspect in how the disease advances; this can be divided into the pulmonary phase and the hyper inflammation phase.

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000 An agency of the European Union

In this kind of scenario, it is important to consider different treatments, not just anti-virals, but also other agents having an immune-modulatory activity have been used and are undergoing clinical trials to understand if they can be of help. To add to the complexity vascular pathological aspects must also be addressed and anti-coagulants are also under evaluation to see if this therapeutic approach is useful. Patients need several interventions in parallel or in sequence to have an impact on mortality.

Many clinical trials are ongoing (see slide 3). It is very important to have large trials to understand as soon as possible which potential treatments work and are safe. We need to go beyond national borders and organise joint trials across EU countries and beyond; to avoid fragmentation of study initiatives, EMA and the European Commission have developed the "ERAvsCORONA" action plan to support large EU clinical trials via an *EU network for adaptive platform trials*.

It normally takes 10-15 years to develop a vaccine – here we are trying to come up with a vaccine as soon as possible and maybe even within a year. Manufacturing also needs to be scaled up to cope with the volume of vaccines that would be needed. Regulators cannot rush any medicines assessment at the expense of risking the safety of subjects with vaccines that have not proven to be effective. See overview of worldwide vaccine development on slide 10.

EMA recognises the importance of continuous dialogue with those involved in medicines development as well as having international collaboration, e.g. EC, ICMRA, WHO, FDA, to move ahead the agenda on therapeutics and vaccines as rapidly as possible.

There followed a Question and Answer session with participants (see recording for details).

1.3 Agency's support for COVID-19 related research and clinical trials

Fergus Sweeney, head of clinical studies and manufacturing taskforce, provided an overview of actions and initiatives that have been taken as well as some statistics regarding ongoing clinical trials.

HMA/EC/EMA have published guidance on the management of clinical trials during COVID-19 covering a range of areas. He highlighted the need for an international coordination to allow the conduct of adequately powered, randomised controlled trials, which can generate sound evidence on the effects of therapeutics and/or vaccines against COVID-19 (see presentation). Too many small trials are conducted mostly in one Member State, whereas fewer, larger, well designed trials are what is needed to progress research on potential treatments for COVID-19 patients. He described the level of ongoing activity in relation to guidance on the management of clinical trials during COVID-19. The European Commission has launched a 'one-stop-shop' on coronavirus research and innovation funding: https://ec.europa.eu/info/research-and-innovation/research-area/health-research-and-innovation/coronavirus-research-and-innovation_en.

Xavier Kurz, head of data analytics and methods taskforce, supplemented the previous presentation with information on activities in relation to observational studies (see presentation). Research questions began to emerge very soon after the start of the pandemic regarding outcomes on the use of medicines to treat COVID-19, so the EMA contacted researchers across Europe to collect information from observational studies. The information has been included within a continuously updated tracking table and EMA is making a rolling review of the data from finalised studies to support regulatory evaluations and decision-making. EMA has encouraged researchers to register their study protocol within the EU PAS Register at www.encepp.eu which will help increase collaboration and use of common protocols. EMA has also funded some studies, e.g. Infrastructure for COVID-19 vaccine monitoring, a framework for multicentre collaboration and a pregnancy study (see slide 3 for more details). Finally, EMA has initiated activities within the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance (ENCePP) to facilitate access to high quality data and analysis.

See meeting recording for details on the Question and Answer session following the above

presentations.

1.4 Availability during COVID-19 pandemic

Monica Dias, Policy and Crisis Coordinating Officer, gave an overview of work so far in relation to medicines shortages (see presentation). She explained that improving the availability of medicines authorised in the EU is a key priority for the EU medicines regulatory network and since 2016, a joint "HMA/EMA Task Force on the Availability of Authorised Medicines for Human and Veterinary Use" (TFAAM) has provided strategic support and advice to tackle disruptions in supply of medicines and ensure their continued availability. This is even more important now during the pandemic.

In April 2019, the task force established a single point of contact (SPOC) network to improve information sharing between MS, EMA and the European Commission on shortages of critical medicines. This includes information sharing on alternative medicines available in other Member States. In the context of the COVID-19 pandemic, EMA is going beyond its remit and has initiated a number of activities, such as the EU Executive Steering Group on shortages of medicines caused by major events , and a survey to all MAHs in March 2020 on the impact of the COVID-19 pandemic on the availability of CAPs; also the i-SPOC system which includes a fast-track monitoring system, to help prevent and mitigate supply issues during COVID-19.

Additionally, there is guidance available for companies on measures implemented in the regulatory framework to address challenges arising from COVID-19 - it is regularly updated and should be considered when deciding on mitigation measures for shortages.

See recording for Q&A session.

1.5 Communication to the public during the pandemic

Melanie Carr, head of stakeholders and communication**,** and Marie-Agnes Heine, head of EMA communications, addressed EMA's approach to communicating during this pandemic (see presentation).

Melanie provided an update on how EMA is communicating and providing public health advice on COVID-19. The approach has been to deliver quick, accurate and credible communications and deal proactively with complicated issues, acknowledging what we do and don't yet know. It is vital to communicate rapidly with honest, clear and transparent messages in order to reduce speculation and build public trust.

A dedicated area on EMAs website has been established; https://www.ema.europa.eu/en - members are invited to have a look and share any comments they have. EMA's communication and public engagement departments have been endeavouring to release as much information as possible and since February over 75 updates including press releases, news items, public health communications have been published. COVID-19 is global pandemic so requires a coordinated global response; EMA has been working not only with its EU partners but also the International Coalitions of Medicines Regulatory authorities (ICMRA), as well as the World Health Organization, FDA, Health Canada, TGA Australia and PMDA Japan.

EMA communications have focused on COVID-19 vaccines and therapeutics, availability of medicines during the emergency, public health advice and guidance to companies. EMA has actively engaged with the media which is key to effective crisis response. Now more important than ever to engage with patients and healthcare professionals and Melanie thanked all the organisations for their active collaboration and support in this process.

Marie-Agnes provided some more details on the content of the communications (see from slide 12).

See recording for subsequent Q&A session.

2. HMA/EMA Task Force on availability of authorised medicines

2.1 Update on task force activities

Kristin Raudsepp (HMA) provided an update on the task force, its achievements so far, ongoing activities and what is expected to be accomplished by end of 2020 (see presentation). She explained the 3 working groups: 1 - Marketing of authorised medicinal products, 2 - Supply Chain Disruption and 3 – Communication. The achievements to date include a Guidance on detection and notification of shortages of medicinal products for MAHs, a good practice guidance for communication to the public on medicines' availability issues, creating a link between EMA shortage catalogue and national shortage registers on EMA and HMA websites and improving information sharing within EU network via a Single Point of Contact (SPOC) which is a platform to share information on medicines' availability issues. SPOC monitors the impact of the Covid-19 pandemic on supply and shortages of medicines, and through the i-SPOC system also gathers feedback from Member States on shortage notifications submitted by pharmaceutical companies in the context of the Covid-19 pandemic.

In terms of next steps, the European Medicines Agencies' Network (EMAN) strategy to 2025 includes availability and accessibility of medicines and supply chain challenges in its strategic areas of focus and patients and healthcare professionals have been and will continue to be consulted throughout. The taskforce is finalising a survey to Member States on withdrawal procedures, preparing an EU Regulator's manual - to consolidate the output of the Task Force on availability and, together with the PCWP/HCPWP developing a concept paper on best practices to prevent shortages.

See recording for subsequent Q&A session.

2.2 Update on collection of practices and recommendations from patients, consumers and healthcare professions

Piotr Kolczynski (CPME) presented on behalf of the PCWP/ HCPWP co-rapporteurs involved in the drafting of the HMA/EMA Concept Paper on Best Practices to Prevent Shortages (see presentation).

He highlighted how they have received examples of existing practices and policy recommendations by 12 members of the working parties. The input was analysed into two categories; existing practices on prevention (25) and notification of shortages and policy recommendations (17).

Piotr gave an update on next steps; PCWP/HCPWP will continue work on the draft concept paper and as such WPs' members are further invited to provide input on the presented documents. The WPs can also contribute to the EU institutions' ongoing and forthcoming initiatives on medicine shortages and the WPs will be revising their 2013 the Common Position on Supply Shortages of Medicines. A follow-up workshop on medicine shortages is being considered for 2021.

Following the presentation, a participant asked whether the policy recommendations had been shared with the MEP in charge of the Own-Initiative report at the European Parliament? **=** The response was that not this one, as it was still being developed, but the Common Position on Supply Shortages of Medicines was shared with the MEP.

It was also suggested by a participant that perhaps better guidance from the Commission to Member States on parallel trade is needed.

3. Data protection: Q&A on secondary use of healthcare data

3.1 Electronic Health Records (EHR) – Access, Share, Expand project – objectives

Peter Arlett and Sabine Brosch presented the background, methodology, objectives and deliverables of the EHR project (see presentation). Health data support scientific research and innovation as part of the development and supervision of medicines. The potential for a strengthened evidence base is

currently perceived as being hindered by uncertainties about the correct interpretation of the General Data Protection Regulation (GDPR) in the area of the "secondary use"[1] of health and medical data for medicines and public health purposes.

The EHR project sets itself to address data protection matters on the secondary use of health data for medicines and public health purposes by delivering a set of Questions & Answers (Q&As) that can facilitate compliance with data protection rules including the rights of patients, consumers and healthcare professionals. Working party members have and will be involved in the development of the Q&As. A preparatory discussion paper was circulated for members input in May 2020.

3.2 Secondary use of healthcare data; groundwork for Q&As development

Orsolya Eotvos, EMA's Assistant Data Protection Officer, provided the background on several data protection topics in the context of secondary health data use focusing on compatibility of data processing, the requirement for a legal basis to process personal data, pseudonymisation principles, data retention, transparency, data subject's rights, registries and international data transfers (see presentation).

It was explained that in accordance with the GDPR, health data includes all data pertaining to the health status of a data subject which may reveal information relating to the past, current or future physical or mental health status of the data subject. Processing of personal data including health data for purposes other than those for which the personal data were initially collected (primary purposes) should be allowed where the processing is compatible with those original purposes acknowledging that Article 5(1) of the GDPR provides that further processing for scientific research purposes shall, in accordance with Article 89(1) (i.e. data minimisation principles), not be considered to be incompatible with the initial purposes.

If the above condition is not met, the secondary use requires a standalone legal basis (consent or other possible legal bases) and should comply with data protection requirements as a standalone data processing activity.

3.3 Overview of feedback from stakeholders

Sabine Brosch, Data Protection Coordinator at EMA, finalised the session with an overview of the input gathered so far in relation to shared position papers, publications in the scientific literature, guiding principles and on the strategic reflection within the EMA Regulatory Science to 2025 (see presentation). Key topics that have been raised refer to data protection, data sharing and linkage, ethical principles, cyber security and artificial intelligence.

Sabine called for members to share specific questions and examples which will underpin the drafting of the "Q&A on the GDPR and the Secondary Use of Data for Medicines and Public Health Purposes" by 10 July 2020 to dpconsultation@ema.europa.eu.

Following the presentation, some feedback from participants included the question why limit to the area of pharmaceutical research and medicine when the issues apply across all clinical research = EMA clarified that the coordination of the scientific evaluation of the quality, safety and efficacy of medicinal products is the responsibility of the EMA and therefore the scope is focusing on this remit.

A comment from another member related to the important role of secondary data use to underpin the safe use of medicines in pregnancy. = Peter Arlett explained this is a very good example of cutting through the complexity of data protection - GDPR is not a barrier to well conducted scientific research using health data, but requires further explanation on how the rules can be correctly applied in the

[1] "Secondary use" means data use for secondary (further) purposes which are different from the initial purposes for which the data were collected initially. Such secondary purposes were not explicitly stated at the time of data collection.

context of the development, authorisation and supervision of medicines**.** The Q&As aim to address this**.**

Another member made reference to recitals 33 & 157 of the GDPR. Both recitals aim to clarify the usage of health data for research purposes. It was proposed that harmonisation of national provisions across Member States could address differences in the application of the GDPR. Although the Article 29 Working Party (now European Data Protection Board or 'EDPB') issued many guidelines, they were not always implemented in a consistent manner. This may have led to differences across Member States.

Orsolya explained that while not having legal status, the Q&As will aim to address key principles of data protection, responsible roles and lawfulness of data processing as well as rights of individuals.

A participant highlighted that consent is key at the time of data collection. How can we ensure in practice that consent is 'freely' given, particularly for vulnerable subjects, especially in a hierarchical situation? = Orsolya explained that consent must be freely given, specific, informed, unambiguous, and where consent is used as a justification for processing special categories of data, such as health data, such consent must be explicit (e.g. written statement). Data controllers should pay particular attention to the condition of a "freely given" consent. As stated in the EDPB Guidelines[2] on consent, this element implies real choice and control for data subjects. This indeed might not be present in hierarchical situations or when the patient is in a vulnerable situation due to his/her health conditions. In these cases, other legal bases should be relied on, e.g. legitimate interest of the data controller.

Another participant asked for more information on ways in which controls on data use may be different in the context of the current COVID-19 pandemic. = Orsolya explained that there are provisions which apply to specific situations such as emergency treatments. For example, Recital 46 states that some types of processing may serve both important grounds of public interest and the vital interests of the data subject, e.g. monitoring epidemics and their spread. These exceptional situations, however must be interpreted in a strict manner and compliance with the GDPR must be assured.

[2] Available: https://edpb.europa.eu/our-work-tools/our-documents/guidelines/guidelines-052020-consent-under-regulation-2016679_en